



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-15

November 9, 2001

Tony L. Herring, Owner
Sea Market Inc.
Old Shrimp Road
Stock Island, Florida 33040

Dear Mr. Herring,

We inspected your firm, located at Old Shrimp Road, Stock Island, Florida 33040 on September 11, 2001 and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation causes your fresh fish species susceptible to ciguatera to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at www.fda.gov.

The deviation is as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for fish species susceptible to ciguatera, such as grouper, to control the food safety hazard of ciguatoxin.

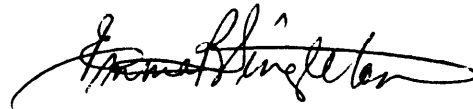
We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct this deviation.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as your written HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviation.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Miss Hromyak at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a stylized flourish extending from the end.

Emma R. Singleton
Director, Florida District